UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

Dean Langford and Nancy Langford, husband and wife, Plaintiffs, v. Zimmer, Inc. and Zimmer Holdings, Inc., Defendants.	**Case No: 03-12245-RCL**

EXHIBIT B TO AFFIDAVIT OF JAMES S. REECE

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

Dean Langford and Nancy Langford, husband and wife, Plaintiffs, v. Zimmer, Inc. and Zimmer Holdings, Inc., Defendants.	**Case No: 03-12245-RCL** **SECOND AMENDED COMPLAINT FOR DAMAGES** **DEMAND FOR JURY TRIAL**

For their claim against Zimmer, Inc. and Zimmer Holdings, Inc. (referred to collectively herein as "Zimmer" or "Defendants"), Plaintiffs Dean Langford (referred to herein as "Mr. Langford") and Nancy Langford (referred to herein as "Mrs. Langford) (referred to collectively herein as "Plaintiffs") state and allege as follows:

PARTIES

1. Plaintiffs are adult individuals and citizens of the State of Florida.

2. Zimmer, Inc., a Delaware corporation, is a subsidiary of Zimmer Holdings, Inc. with headquarters in Warsaw, Indiana.

3. Zimmer Holdings, Inc. (hereinafter "Zimmer") is a Delaware corporation with headquarters in Warsaw, Indiana.

JURISDICTION

4. Plaintiffs are citizens of the State of Florida and Defendants are corporations incorporated under the laws of Delaware with headquarters in Warsaw, Indiana. The matter in controversy exceeds $75,000. Therefore, this Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000.00 and because there is complete diversity of citizenship between Plaintiffs and Defendants.

GENERAL BACKGROUND

5. At all relevant times, Zimmer has been engaged in the development, design, manufacture, production, testing, labeling, marketing, advertising, sale, promotion and/or distribution of orthopaedic reconstructive implants and fracture management products, including artificial hips and other joints.

6. Zimmer, Inc. was founded in 1926, purchased by Bristol-Myers Company in 1972, and spun off from Bristol-Myers-Squibb in August 2001.

7. Zimmer Holdings, Inc. was created in January 2001, and upon information and belief assumed all of the liabilities of Zimmer, Inc. at the time it was spun off.

8. Upon information and belief, Zimmer has sold the relevant products throughout the United States and in foreign countries.

9. At all relevant times, Zimmer has held itself out to the public as a leader in orthopaedic knowledge. According to its own public statements, Zimmer's "vision" is "to be the global leader in enhanced quality of life for orthopaedic patients. To place confidence in the surgeons' skilled hands. To reaffirm our traditions, inspire our future and ensure our success through each patient's new freedom." Zimmer's "mission" is "to develop, produce and globally market the highest quality orthopaedic product and services that repair, replace and regenerate. Through the hands of skilled surgeons, we will enhance patient quality of life." Zimmer's stated "values" include a "pledge to quality" holding that "[p]atients trust that our life's work will safely and effectively improve their lives. We are committed to defect-free products." Zimmer's public representation is that "[t]he Zimmer brand represents excellence in our industry and the highest-quality products and services."

10. Zimmer's products include hip implant systems designed to simulate and replace the natural hip.

11. The hip joint is a ball and socket joint and is formed where the rounded head of the thigh bone (femur) moves within the acetabular socket of the pelvis. In a total hip replacement surgery, the painful parts of the damaged hip are replaced with artificial hip parts usually consisting of a metal femoral stem, metal femoral head, polyethylene acetabular liner, and metal acetabular shell. Hip replacement surgery and the components used in that surgery are discussed in Zimmer publications entitled "Guide to Hips" and "Your Hip Surgery."

12. There are two primary methods of securing hip implant femoral stems in the femoral canal: cemented and cementless. In both methods, the head and neck of the femur is cut off. The hollow center portion of the remaining femur is reamed out. In the cemented method, a rapid-setting polymeric bone cement (grout) is prepared at the time of surgery and injected into the bone canal. The stem of the femoral component of the hip is positioned within the canal with the grout holding it in position after the grout sets. This method of implantation was pioneered by Sir John Charnley in the late 1950s and early 1960s and has been used to secure various joint replacement components in bone ever since.

13. According to a commentator writing in the authoritative *Journal of Arthroplasty*, Vol. 15 No. 8 (2000), "[b]y the mid- to late 1980s, it generally was accepted that stem fixation was not a major issue in THA. It was thought that consistent fixation could be achieved in the 10- to 20- year time frame in more than 90% of cases with cemented or cementless stem fixation."

14. Despite such success in existing implant design, and in order to increase market share, Zimmer decided to dramatically change the surface configuration of some of its femoral stems. It did so beginning in the mid to late 1980s by roughening and/or texturing the surface of

its femoral stems and precoating portions of the stems with a commonly used bone cement polymer, polymethylmethacrylate (PMMA).

15. This design change was to increase the bond at the cement-metal interface and prevent loosening by essentially creating the cement-metal bond during manufacturing and thus making the bond created during surgery one of cement-on-cement rather than cement-on-metal. According to Zimmer documents, "[p]artial failure of the interface places the remaining well-bonded areas in a state of much higher stress which then accelerates deterioration of the remaining bond area." Zimmer also claimed that a "combination of implant surface texturing and polymeric coating has been demonstrated to improve the mechanical reliability of the implant-bone cement interface. Laboratory and clinical investigations have shown this approach to be effective in improving the immediate and long-term adhesion of the implant to the cement."

16. In 1987 Zimmer received United States Patent 4,795,472, for a prosthesis with enhanced surface finish for which it claimed, "[t]he resulting implant which includes the textured surface underneath the polymer precoat provides an increased surface area of contact with the fresh bone cement at the time of implantation, thus enhancing the bonding of the precoated implant to the new bone element… ."

17. Zimmer manufactured and marketed roughened hip stems pre-coated with PMMA from 1986 through the present. A family of products was produced including Iowa Grit-Blasted, Harris Precoat, Precoat Plus, Centralign, and VerSys-Plus. Only the VerSys-Plus remains in production.

18. On information and belief, Zimmer was the only manufacturer to roughen and PMMA precoat its stems.

19. Each of these femoral stems, Iowa Grit-Blasted, Harris Precoat, Precoat Plus, Centralign, and VerSys Plus, performed poorly. Each of these femoral stems has been the subject of peer reviewed journal articles that objectively demonstrated substandard performance. Respected orthopedic surgeons called for the abandonment of each of these femoral stems (including some of the physicians who participated in their design).

20. With regard to the Iowa Grit-Blasted stem, for example, one of its creators wrote in a leading orthopaedic journal:

> The use of femoral components with a matte finish, and more dramatically with a grit blasted surface finish, produced more osteolysis and significantly more femoral revisions when compared with the polished Charnley femoral component in the younger patient population. (The primary author has returned to using a polished surface finish of the femoral component based on these observations…)

Callaghan, Johnston, and Pedersen, *The John Charnley Award: Practice Surveillance: A practical method to assess outcome and to perform clinical research.* Clinical Orthopaedics & Related Research, 369:25-28 (1999).

21. With regard to the Harris Precoat and Precoat Plus, another group of authors noted:

> The rate of failure of a modern precoated femoral component was found to be higher than one would have anticipated and stands in marked contrast to the failure rate of an older prosthesis with nearly twice the duration of follow-up. The causes of failure are multifactorial, but it would appear that an important element in the present series was the design and surface treatment of the femoral component, including the increased surface roughness and precoating with methylmethacrylate.

Ong, Wong, Lai, Garino and Steinberg, *Early Failure of Precoated Femoral Components in Primary Total Hip Arthroplasty*, Journal of Bone and Joint Surgery, 84(5):786-792 (2002).

22. With regard to the VerSys Plus, one author has written that its precoated components "have revealed higher than expected early loosening rates" despite design

modifications such as stem length, geometry, and surface finish. The author reviewed 72 Zimmer VerSys Plus precoated femoral components implanted during 1997-1998 by two surgeons. At 3-4 year follow-up, the incidence of aseptic loosening necessitating revision surgery was 11% (nine patients). Osteolysis was severe and progressing rapidly and "three hips developed pathologic subtrochanteric stress fractures as a result of loosening and osteolysis." According to the author, "[w]hen loosening develops, the extent of osteolysis is more dramatic than what is normally seen around loose hip implants." The author does not advocate the use of PMMA precoated femoral components for THA. K.A. Ezzet, *Unacceptable failure with a currently available PMMA-precoated femoral component in total hip arthroplasty (Zimmer VerSys-Plus)*, Abstract from the Association of Hip and Knee Surgeons (Nov. 2001).

23. The Iowa Grit-Blasted, Harris Precoat, and Precoat Plus stems mode of failure often involved debonding, or separation, of the interface between the precoat cement (grout) and the metal femoral stem. Wear debris consisting of tiny particles of bone cement and polyethylene or metal from the implant articulating surfaces enter the gap created by the debonding and then elicit a response from debris scavenger cells (phagocytes). Thus activated, these cells then secrete substances that activate bone-consuming cells (osteoclasts). Local bone loss (osteolysis) is the end result of this biologic process that begins when the number of wear particles generated in the joint space overwhelms the capsule's capacity to clear them. The loss of bone often results in implant loosening. The loose (unstable) implant then often becomes painful and must be removed and replaced surgically. Compared to successful primary hip replacement, this "revision surgery" is more difficult to achieve and sometimes produces a less satisfactory result. (This mode of failure is the same with regard to the VerSys Plus.)

24. The problem of debonding and osteolysis was well known to Zimmer as was the poor performance of the Iowa Grit-Blasted, Harris Precoat, and Precoat Plus stems. Zimmer stopped producing and marketing them.

THE ZIMMER CENTRALIGN

25. Despite the failure of these roughened, pre-coated stems, Zimmer introduced a new version, the Centralign, beginning in 1992.

26. Mr. Langford is an individual who used the Zimmer Centralign prosthesis and has suffered damage as a direct result of its defective nature and its premature failure.

27. Zimmer aggressively marketed the Centralign claiming:

a) The Zimmer *Centralign* Precoat Hip Prosthesis is designed to achieve unparalleled cemented hip implant stability. Starting with the time-tested design of the **Harris Precoat Plus** Hip Prosthesis, Zimmer engineering has added several important new innovations to help promote long-term implant performance.

b) **Implant Stability For Long-Term Clinical Results**
The improved bond, provided by PMMA precoating combined with the thicker, more uniform cement mantle, attacks the most common causes of implant loosening. These innovative advances help promote superior long-term implant performance.

c) **Increased Fixation Promotes Long-Term Implant Stability**
The effectiveness of the Zimmer exclusive PMMA precoat process is well documented [citing to its own *marketing piece*]. During the manufacturing process, a thin film of PMMA is applied to the textured implant surface. This provides an intimate PMMA-metal bond formed in a controlled environment. The combination of precoating and texturing can nearly triple the fatigue strength of the cement/metal interface.

d) Proximal macrotexturing together with proximal and distal poly methylmethacrylate (PMMA) precoating optimizes the cement-metal interface at the two critical areas where peak stresses occur. This unique combination of PMMA precoating and macrotexturing more than doubles the tensile strength and yields an eight-fold increase in the shear strength of the cement-metal bond.

e) *CENTRALIGN* PRECOAT

The *Centralign* Precoat creates the new standard for fixation and performance in total hip arthroplasty.

f) The *Centralign* Precoat stem is designed to optimize the interface between the metal and cement. This is a critical interface in the stability of the cement-bone-metal composite. By far the most common radiographic sign of failure of fixation of a cemented femoral component is the development of a radiolucent zone between the implant and the cement at the proximal lateral portion of this interface, as seen on an AP (anterior-posterior) X-ray film. This X-ray appearance represents failure of this interface, or debonding.

Direct measurements of the strain by strain gauges in the bone cement adjacent to the metal stem have shown that the strain in the cement is greatly increased when this interface fails. It is well known that the shear strength of this interface is approximately only one-fifth of the shear strength of the cement itself. Since the shear strength of the bone cement is already a low value, the interface shear strength is a manifestly vulnerable element in the longevity of fixation. Moreover, this interface is attacked by the saline environment in the body and becomes even weaker with time.

Two features of the *Centralign* Precoat surface substantially strengthen this interface and each augments the other in making it stronger. The textured surface increases the interface shear strength by a factor of three by its contour alone. By itself this is an advantage, but is incomplete in strengthening the interface because the cement-metal interface is also subject to tension in the normal loading of the hip join [sp] in gait and stair climbing. Texturing the metal surface does not increase resistance to tensile forces. To strengthen the interface in tension requires **precoating**, which increases the strength of the metal-cement interface both in shear and tension. Thus, the complementary actions of the roughened surface and the precoating increase the shear strength by a factor of eight and the tensile strength by two. Moreover, precoating reduces the loss of strength of this interface by the action of the saline environment and, thus, maintains the increased strength over time.

g) **Improved Longevity**
The increased stability achieved by the *Centralign* Precoat Hip Prosthesis makes it the optimum choice for long-term implant performance.

28. The representations enumerated above, along with others made by Zimmer about the Centralign Precoat Hip Prosthesis, were false and misleading in a number of ways, including the following: clinical results indicate that in actual use, the interface between the metal and

cement was never optimized; the shear strength of the interface was not increased by a factor of eight; the tensile strength was not increased by a factor of two; the strength of the interface was not increased over time especially in the body's saline environment; the Centralign did not promote long-term implant stability; and the Centralign did not provide superior long-term performance.

29. In fact, the performance of the Centralign was substandard: it failed earlier than other stems; it failed more severely; it resulted in massive osteolysis; it required frequent revisions; it caused an enormous amount of pain, disability and medical expense for patients in whom it was implanted; and it was defective in other ways.

30. Studies in peer-reviewed journals have documented the poor performance of the Centralign Precoat Hip Prosthesis. Examples include:

a. Sylvain, Kassab, Coutts and Santore, *Early Failure of a Roughened Surface, Precoated Femoral Component in Total Hip Arthroplasty*, The Journal of Arthroplasty, 16(2): 141-148 (2001):

> This series, with a 12% mechanical failure rate at <3 year average follow-up, raises serious concerns about the utility of this femoral prosthesis, particularly in high-demand patients. The failure rate reported here at 3 years would be considered unacceptable at 10-year follow-up. Caution must be exercised when deciding on a roughened surface, PMMA-precoated prosthesis until the mechanisms of failure seen in these series are understood better.

b. Duffy, Muratoglu, Biggs and Harris, *The Negative Effect of Proximal Macrotexturing on the Cement Metal Interface of Cemented Femoral Components: An Experimental and Clinical Retrieval Analysis*, Poster Session at the 47th Annual Meeting, Orthopaedic Research Society (2002):

> These data indicate that proximal macrotexturing on femoral components has a negative effect. Volcanoes and "caldera" are formed at the cement-metal interfaces. These weaken the bond at this area of high stress, and may have contributed to debonding. When motion occurs at this interface, cement debris occurs. This debris could contribute to osteolysis. These data recommend against macrotexturing of femoral components with these designs.

c. High Rate of Early Catastrophic Failure and Periprosthetic Fracture with a Precoated Centralized Component in Total Hip Arthroplasty
by K. Ezzet
Poster Session of the 64th Annual Meeting, Western Orthopaedic Association, 2000:

> In 1996 and 1997, 226 primary total hip arthroplasties were performed at the author's institution utilizing a proximally and distally PMMA precoated femoral component, also employing proximal and distal PMMA centralizers. At 24-48 month follow-up, 19 patients (8.4%) have undergone revision for aseptic femoral loosening and massive femoral osteolysis. Six patients (2.6%) experienced pathologic periprosthetic fracture due to osteolysis. The initial failure mode was de-bonding of the prosthesis from the cement. Debonding was usually followed by a rapid, aggressive intertrochanteric and subtrochanteric osteolysis. The rapidity and extent of osteolysis was substantially greater than usually observed with loose femoral components. Based on these findings, the author does not advocate pre-coated femoral components and recommends early revision once loosening is identified. This author was not involved with the primary surgeries, but was involved in the revisions, and was thereby able to carry out an unbiased investigation of these failures.

31. Zimmer knew of the problems associated with the Centralign hip prosthesis but did not notify Mr. Langford's doctors, who implanted the Centralign Precoat stem or Mr. Langford.

32. By failing to include complete and accurate warnings and information to physicians and potential patients, Zimmer withheld important information regarding the safety of the prosthesis.

33. Zimmer, by affirmative misrepresentations and omissions, falsely created the impression that the Centralign hip prosthesis was free of defects, would not cause or accelerate certain serious medical conditions and injuries, and would continue to function in a normal fashion for an acceptable period of time.

PLAINTIFF'S INJURY

34. Following a history of lower extremity symptoms, on or about April 25, 1992, Mr. Langford was implanted with a Centralign hip prosthesis and other Zimmer hip products, including a femoral head, an acetabular component and acetabular liners while a patient at Massachusetts General Hospital in Boston, Massachusetts.

35. Sometime thereafter, after an unacceptably short period of use, diagnostic studies and examination results revealed failure of the Centralign hip prosthesis and one or more of the other Zimmer hip products.

36. As a direct result of the failure of the Centralign hip prosthesis and one or more of the other Zimmer hip products after an unacceptably short period of use, Mr. Langford required surgical removal and replacement of the failed Centralign prosthesis and other Zimmer hip products that took place on March 27, 2001 at St. Luke's Hospital in Jacksonville, Florida.

37. On information and belief, Mr. Langford received a Zimmer hip product or products during the revision surgery of March 27, 2001. As a direct result of the failure of one or more Zimmer hip products, Mr. Langford required another hip operation on or about April 1, 2003.

38. As a direct result of the fault of Defendants, plaintiffs have suffered injuries including the following: Mr. Langford sustained severe and permanent injuries to his left lower extremity, as well as other injuries; Mr. Langford sustained severe and permanent injuries because he and his doctors were not adequately informed about the full extent of the medical problems which can be caused by premature loosening of the Centralign hip prosthesis; as a result, he has in the past and will in the future incur medical and hospital expenses for the treatment of these injuries; as a result he has sustained a loss of wages and other compensation and a diminution of his earning capacity; as a result he and Mrs. Langford have incurred and will

in the future incur additional expenses for activities he would have otherwise done himself; as a result he has in the past and will in the future suffer great physical and mental pain and suffering, disfigurement and related damages; as a result, Mrs. Langford has been injured and has suffered damages because the love, companionship, affection, society, sexual consortium, comfort and physical support, which she previously received from her husband has been diminished and will continue to be diminished in the future. As a result, Plaintiffs each have been damaged and injured in an amount greater than $75,000.00.

COUNT I
Negligence

39. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 38 of this Complaint as though set forth herein.

40. Defendants had a duty to exercise reasonable care in the development, design, manufacture, production, testing, labeling, marketing, advertising, sale, promotion, and/or distribution of the Centralign hip prosthesis and other Zimmer hip products implanted in Mr. Langford (other Zimmer hip products). This duty included a duty to assure that the products did not cause users to suffer from unreasonably dangerous or serious health risks which were foreseeable to Defendants.

41. Defendants failed to exercise ordinary care in the development, design, manufacture, production, testing, labeling, marketing, advertising, sale, promotion, and/or distribution of the Centralign hip prosthesis and other Zimmer hip products in that Defendants knew or should have known that the prosthesis and other Zimmer hip products created a foreseeable and/or high risk of serious medical conditions and injuries.

42. Defendants were negligent in the development, design, manufacture, production, testing, labeling, marketing, advertising, sale, promotion, and/or distribution of the Centralign hip prosthesis and other Zimmer hip products in that they:

a. failed to use due care in the development, design, manufacture, and production of the prosthesis and other Zimmer hip products so as to avoid the aforementioned risks to individuals such as Plaintiff in whom the products were implanted;

b. failed to accompany the products with proper warnings regarding the aforementioned risks associated with the prosthesis and other Zimmer hip products;

c. failed to provide warnings that accurately reflected the symptoms, scope or severity of the serious medical risks;

d. failed to conduct adequate testing and/or post-marketing surveillance to determine the safety of the prosthesis and other Zimmer hip products;

e. failed to provide adequate information to physicians concerning the prosthesis and other Zimmer hip products;

f. failed to adequately convey to physicians and patients (while actively encouraging the sale of the prosthesis), a number of important facts about the prothesis, including the following: 1) the prosthesis can cause accelerated loosening of itself within the femoral cavity; 2) the prosthesis can cause accelerated debonding of the cement fixation mantle from the femur; 3) the prosthesis can cause cracking or accelerated cracking of the cement mantle around the prosthesis; 4) the prosthesis can cause accelerated debonding of the prothesis from the cement fixation mantle; 5) the prosthesis can cause osteolysis or accelerated osteolysis of

bone that adjoins the prosthesis or the cement mantle around the prosthesis; 6) the prosthesis can cause femoral bone loss; 7) the prosthesis can cause conditions that would reasonably require a premature replacement of the prosthesis; and 8) the prosthesis can cause conditions that would make a replacement operation more difficult;

g. failed to adequately convey to physicians and patients (while actively encouraging the sale of the other Zimmer hip products), a number of important facts about these products, including the following: (1) one or more of these products can cause premature loosening or failure of these products or the Centralign hip prosthesis; (2) one or more of these products can cause osteolysis or accelerated osteolysis of bone in the hip; (3) one or more of these products can cause bone loss in the hip; (4) one or more of these products can cause conditions that would reasonably require a premature replacement of these products or the Centralign hip prosthesis; and (5) one or more of these products can cause conditions that would make a revision operation more difficult; and

h. were otherwise careless or negligent.

43. Despite the fact that Defendants knew or should have known that the Centralign hip prosthesis and other Zimmer hip products could cause serious medical conditions and injuries in patients, such as those set forth in paragraphs 42(f) and 42(g), Defendants continued to market the prosthesis and other Zimmer hip products to physicians and patients, including Mr. Langford's doctors and Mr. Langford, when there were more appropriate alternative prostheses and hip products.

44. Defendants knew or should have known that patients, such as Mr. Langford, would suffer serious medical conditions and injuries as a result of Defendants' failure to exercise ordinary care as described herein.

45. As a direct result of the negligent conduct of the Defendants, Plaintiffs have suffered damages as described herein.

COUNT II
Strict Product Liability (Failure to Warn)

46. Plaintiffs hereby incorporate by reference the allegations set forth in paragraphs 1 through 45 inclusive as though fully set out herein.

47. Defendants are the manufacturers, sellers, and/or distributors of the Centralign hip prosthesis and other Zimmer hip products. The prosthesis and other Zimmer hip products were not accompanied by proper and adequate warnings regarding serious medical conditions and injuries that could be caused by the prosthesis and other Zimmer hip products and Defendants failed to effectively and accurately warn physicians and patients about such risks.

48. Prior to the time the Centralign Precoat stem and other Zimmer hip products were implanted in Mr. Langford, Zimmer knew, or should have known, that the prosthesis and other Zimmer hip products were dangerously defective products that posed unacceptable risks of serious medical conditions and injuries, such as those set forth in paragraphs 42(f) and 42(g).

49. Subsequent to the time the Centralign Precoat stem and other Zimmer hip products were implanted in Mr. Langford, Zimmer knew, or should have known, that the prosthesis and other Zimmer hip products were dangerously defective products which posed unacceptable risks of serious medical conditions and injuries such as those set forth in paragraphs 42(f) and 42(g) and required increased medical monitoring to determine signs of early failure and to prevent further damage as a result of premature failure.

50. Despite such knowledge both before and after the Centralign Precoat stem and other Zimmer hip products were implanted in Mr. Langford, Zimmer failed to warn either Mr. Langford or his doctor about such dangers inherent in the use of the Centralign Precoat stem and other Zimmer hip products and the need for frequent medical monitoring in patients such as Mr. Langford who were implanted with the products.

51. As a direct result of the defective and unreasonably dangerous condition of the prosthesis and other Zimmer hip products as sold and/or distributed by Defendants, Plaintiffs have suffered damages as described herein.

COUNT III
Strict Product Liability (Defective Design, Manufacture and Testing)

52. Plaintiffs hereby incorporate by reference the allegations set forth in paragraphs 1 through 51 inclusive, as though fully set out herein.

53. The prosthesis developed, designed, manufactured, produced, tested, labeled, marketed, advertised, sold, promoted and/or distributed by Defendants was defective and unreasonably dangerous for a number of reasons, including the following:

a. the prosthesis can cause accelerated loosening of itself within the femoral cavity;

b. the prosthesis can cause accelerated debonding of the cement fixation mantle from the femur;

c. the prosthesis can cause cracking or accelerated cracking of the cement mantle around the prosthesis;

d. the prosthesis can cause accelerated debonding of the prothesis from the cement fixation mantle;

e. the prosthesis can cause osteolysis or accelerated osteolysis of bone that adjoins the prosthesis or the cement mantle around the prosthesis;

f. the prosthesis can cause femoral bone loss;

g. the prosthesis can cause conditions that would reasonably require a premature replacement of the prosthesis; and

h. the prosthesis can cause conditions that would make a replacement operation more difficult.

54. The other Zimmer hip products developed, designed, manufactured, produced, tested, labeled, marketed, advertised, sold, promoted and/or distributed by Defendants were defective and unreasonably dangerous for a number of reasons, including the following: (1) one or more of these products can cause premature loosening or failure of these products or the Centralign hip prothesis; (2) one or more of these products can cause osteolysis or accelerated osteolysis of bone in the hip; (3) one or more of these products can cause bone loss in the hip; (4) one or more of these products can cause conditions that would reasonably require a premature replacement of these products or the Centralign hip prosthesis; and (5) one or more of these products can cause conditions that would make a revision operation more difficult.

55. As a direct result of the defective and unreasonably dangerous condition of the prosthesis and other Zimmer hip products developed, designed, manufactured, produced, tested, labeled, marketed, advertised, sold, promoted, and/or distributed by Defendant, Plaintiffs have suffered damages as described herein.

COUNT IV
Breach of Express Warranties

56. Plaintiffs hereby incorporate by reference the allegations set forth in paragraphs 1 though 55 inclusive, as though fully set out herein.

57. At all times material hereto, Defendants expressly warranted, among other matters, that the Centralign hip prosthesis and other Zimmer hip products had increased stability

and/or longevity and other features. The prosthesis and other Zimmer hip products do not conform to these express representations for at least the reasons set forth in Count III.

58. As a direct result of such breach of express warranties, Plaintiffs have been damaged as described herein.

COUNT V
Breach of Implied Warranties

59. Plaintiffs hereby incorporate by reference the allegations set forth in paragraph 1 through 58 inclusive, as though fully set out herein.

60. At the time Defendants developed, designed, manufactured, produced, tested, labeled, marketed, advertised, sold, promoted, and/or distributed the Centralign hip prosthesis and other Zimmer hip products for use by Mr. Langford, Defendants knew of the use for which the prosthesis and other Zimmer hip products were intended and impliedly warranted the products to be of merchantable quality and safe and fit for their intended use. Contrary to such implied warranties, the prosthesis and other Zimmer hip products were not of merchantable quality or safe or fit for their intended use.

61. As a direct result of the Defendants' breach of implied warranties, Plaintiffs have been damaged as described herein.

COUNT VI
Unfair or Deceptive Acts or Practices

62. Plaintiffs hereby incorporate by reference the allegations set forth in paragraphs 1 through 61 inclusive, as though fully set out herein.

63. Defendants are companies engaged in trade or commerce.

64. Defendants engaged in unfair and/or deceptive acts or practices in their development, design, manufacture, production, testing, labeling, marketing, advertising, sale,

promotion, and/or distribution of the Centralign precoat stem, including but not limited to the following:

a. Defendants consciously chose to ignore the role of the Centralign hip prosthesis as a cause in the growing numbers of reports of premature loosening of this implant in patients;

b. Defendants consciously chose to tell the orthopedic community that premature loosening of the Centralign hip prosthesis was related solely to factors other than the Centralign, despite lacking evidence to support these statements;

c. Defendants consciously chose to hide the fact that greater than normal bone loss, which can lead to additional medical complications was caused by the loosening of the Centralign hip prosthesis; and

d. Defendants consciously chose to engage in these and other unfair and deceptive acts and practices, despite knowing that close and prompt monitoring of patients whose Centralign hip prostheses were prematurely loosening could help reduce the amount of bone loss caused by the loosening, and could prevent further serious injury to them.

65. Defendants willfully and knowingly engaged in these unfair and deceptive acts and practices, in blatant disregard for the health and safety of patients with Centralign hip prostheses, including Mr. Langford.

66. The demand requirements of Mass. Gen. Laws Ann. ch. 93A, § 9(3) do not apply because the Defendants do not maintain a place of business or keep assets within the commonwealth of Massachusetts.

67. As a direct result of the Defendants' unfair and deceptive acts and practices, Plaintiffs have suffered damages as described herein.

COUNT VII
Loss of Consortium

68. Plaintiffs hereby incorporate by reference the allegations set forth in paragraphs 1 through 67 inclusive, as though fully set out herein.

69. Mrs. Langford is Mr. Langford's wife.

70. As a direct and proximate result of the injuries sustained by Mr. Langford, Mrs. Langford has been injured and has suffered damages because the love, companionship, affection, society, sexual consortium, comfort and physical support that she previously received from her husband has been diminished and will continue to be diminished in the future.

WHEREFORE, Plaintiffs pray for judgment against Defendants as follows:

a. For damages as are fair and reasonable; and

b. For attorneys' fees and costs pursuant to Mass. Gen. Laws Ann. ch. 93A, § 9(3A); and

c. For double or treble damages pursuant to Mass. Gen. Laws Ann. ch. 93A, § 9(3A); and

d. For such other and further relief as this Court deems just and proper.

Dated this _____ day of July, 2004.

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